



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/564,452	01/12/2006	Christina Ammann	112701-703	8957				
29157 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690	7590 04/02/2009		<table border="1"><tr><td>EXAMINER</td></tr><tr><td>GWARTNEY, ELIZABETH A</td></tr></table>		EXAMINER	GWARTNEY, ELIZABETH A		
EXAMINER								
GWARTNEY, ELIZABETH A								
			<table border="1"><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1794</td><td></td></tr></table>	ART UNIT	PAPER NUMBER	1794		
ART UNIT	PAPER NUMBER							
1794								
			<table border="1"><tr><td>NOTIFICATION DATE</td><td>DELIVERY MODE</td></tr><tr><td>04/02/2009</td><td>ELECTRONIC</td></tr></table>	NOTIFICATION DATE	DELIVERY MODE	04/02/2009	ELECTRONIC	
NOTIFICATION DATE	DELIVERY MODE							
04/02/2009	ELECTRONIC							

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary

Application No.

10/564,452

Applicant(s)

AMMANN ET AL.

Examiner

Elizabeth Gwartney

Art Unit

1794

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The Amendment filed 01/14/2009 has been entered. Claims 3-4 have been cancelled. Claims 1-2 and 5-14 are pending.
2. The *previous* claim objections and 2nd Paragraph rejections have been withdrawn in light of applicant's amendments made 01/14/2009.

Claim Objections

3. Claims 1-2 and 5-15 are objected to because of the following informalities: Regarding claims 1 and 10-15, the terms "fiber" and "fibre" are used interchangeably within the claims. Further, with regards to claims 1-2 and 5-15, the term "fibre" should be spelled according to US English, i.e. fiber and used consistently within and among the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-2 and 5-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While there is support for a source of dietary fiber comprising 20-40% by weight soluble non-starch polysaccharides, 30-60% insoluble non-starch polysaccharides and 20-40% oligosaccharides (p.5/L27-29) or about 29% acacia gum, about 29% oligosaccharides and about 43% insoluble fiber (p.13/Fibre), there is no support for a source of dietary fiber comprising 30-60% insoluble fiber.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-2 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spivey-Krobath et al. (WO 02/39834) in view of Brassart et al. (US 6,489,310).

Regarding claims 1-2 and 5 Spivey-Krobath et al. disclose a liquid or powdered reconstitutable nutritional composition (Abstract, p.5/L35- p.6/L3, p.8/L14-18) comprising a protein source, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.3/L15-17, p.5/L5, p.10/Table 1). Spivey-Krobath et al. also disclose a composition wherein the source of fiber comprises 70% by weight fructooligosaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligosaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructooligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance

of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not too viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Regarding claim 6, modified Spivey-Krobath et al. disclose all of the claim limitations as set forth above. Given that modified Spivey-Krobath et al. disclose a nutritional composition identical to that presently claimed, it is clear that the composition would inherently possess the recited viscosity.

Regarding claim 7, modified Spivey-Krobath et al. disclose all of the claim limitations as set forth above. While modified Spivey-Krobath et al. disclose a nutritional composition with 10.5 g protein/100 ml, the reference does not explicitly disclose 4.5-6.0 g protein/100ml. As

caloric content and energy density are variables that can be modified, among others, by adjusting the protein content of the nutritional composition, the precise protein content would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed protein content cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the protein content of the nutritional composition disclosed by modified Spivey-Krobath et al. to obtain the desired balance between caloric content and energy density (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 8, modified Spivey-Krobath et al. disclose all of the claim limitations as set forth above and that the composition comprises a source of lipids (p.7/L8-14, p.10/Table 1).

Regarding claim 9, Spivey-Krobath et al. disclose all of the claim limitations as set forth above. Given that modified Spivey-Krobath et al. disclose a nutritional composition identical to that presently claimed, since lactose is not disclosed, it is clear that the composition would inherently be clinically free of lactose.

Regarding claims 10-12 and 14-15, modified Spivey-Krobath et al. disclose all of the claim limitations as set forth above. Spivey-Krobath also disclose administering an effective amount of a powdered or liquid reconstitutable nutritional composition (Abstract, p.5/L35-p.6/L3, p.8/L14-18) comprising a protein source, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of

4 g. to about 50 g per 300 g of the composition (Abstract, p.1/L7-8, p.3/L15-17, 30-32, p.5/L5, p.10/Table 1). Further, Spivey-Krobath et al. disclose a composition wherein the source of fiber comprises 70% by weight fructooligosaccharide (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligosaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not too viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Regarding the intended use of the method, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Further, given that modified Spivey-Krobath et al. disclose method as presently claimed, it is clear that such method would intrinsically improve the digest tract and bowel function of a patient, inherently enhance mucosal barrier function in a patient, inherently promote gut health or comfort in an elderly patient, inherently maintain or restore a well-balanced gut flora, and inherently enhance mucosal function in a human individual.

Regarding claim 13, Spivey-Krobath et al. disclose a method for preparing a nutritional composition comprising the steps of mixing a liquid or powdered reconstitutable nutritional composition comprising a protein source, a source of digestible carbohydrates, and a source of dietary fiber, having an energy density of 1.6 kcal/ml and dietary fiber in an amount of 4 g. to about 50 g per 300 g of the composition (Abstract, p.1/L7-8, p.3/L15-17, 30-32 p.10/Table 1); and hydrating the components to provide a liquid mixture (see blending the required constituents - p.9/L1, see dissolved instantaneously in water to provide a beverage - p.6/L2). Spivey-Krobath et al. also disclose a composition wherein the source of fiber comprises 70% by weight fructooligosaccharid (i.e. oligosaccharide) and 30% by weight inulin (i.e. soluble fiber (p.10/Table 1) or a combination of fructooligosaccharide (i.e. soluble non-starch polysaccharide) and acacia gum (i.e. soluble non-starch polysaccharide) (p.5/L5-6).

Spivey-Krobath et al. does not explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber).

Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructooligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

Spivey-Krobath et al. and Brassart et al. are combinable because they are concerned with the same field of endeavor, namely, nutritional compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not too viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

11. Claims 1-4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brassart et al. (US 6,489,310) in view of Spivey-Krobath et al. (WO 02/39834).

Regarding claims 1-2 and 5, Brassart et al. disclose a liquid or powdered and reconstitutable nutritional composition (C5/L52-60) comprising a protein, a source of digestible carbohydrates and a source of dietary fiber (Abstract) having an energy density of 0.7 -1.5 kcal/100ml (C5/L49-51) and dietary fiber in an amount of 1.2g/100ml (C7/Example 1/L23). Brassart et al. also disclose that the source of fiber comprises 5-30% inulin (soluble fiber), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble fiber) (C4/L40-44).

Brassart et al. does not explicitly disclose that the nutritional composition comprises in excess of 2.5 g/100 ml or a soluble fiber including acacia gum.

Spivey-Krobath et al. teach that is was known to use a soluble fiber, including acacia gum, as part of a nutritional composition (p.5/L5). Given that acacia gum is a well known source of soluble fiber used for nutritional compositions, since Brassart et al. disclose a soluble fiber as part of a fiber blend, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of Brassart et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

While Brassart et al. disclose a nutritional composition with 1.2g/100ml dietary fiber the reference fails to disclose levels in excess of 2.5g/100ml. As viscosity is a variable that can be modified, among others, by adjusting the dietary fiber in the nutritional composition, the precise amount of dietary fiber would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed content of dietary fiber cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of dietary fiber in the nutritional composition of Brassart et al. to obtain the desired balance between product viscosity and the nutritional benefits of dietary fiber (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 6, modified Brassart et al. disclose all of the claim limitations as set forth above. Given that Brassart et al. disclose a nutritional composition identical to that presently claimed, it is clear that the composition would inherently possess the recited viscosity.

Regarding claim 7, modified Brassart et al. disclose all of the claim limitations as set forth above. While Brassart et al. disclose a nutritional composition with 3.8 g protein /100 ml, the reference does not explicitly disclose 4.5-6.0 g protein/100ml. As caloric content and energy density are variables that can be modified, among others, by adjusting the protein content of the nutritional composition, the precise protein content would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed protein content cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the protein content of the nutritional composition disclosed by modified Brassart et al. to obtain the desired balance between caloric content and energy density (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 8, modified Brassart et al. disclose all of the claim limitations as set forth above and that the composition comprises a source of lipids (Abstract, C5/L12-38).

Regarding claim 9, modified Brassart et al. disclose all of the claim limitations as set forth above. Given that Brassart et al. disclose a nutritional composition identical to that presently claimed, since lactose is not disclosed, it is clear that the composition would inherently be clinically free of lactose.

Regarding claims 10-12 and 14-15, Brassart et al. disclose all of the claim limitations as set forth above. Brassart also disclose administering the nutrition composition (C6/40-44, C8/Example 8/L2-5) of a liquid or powdered and reconstitutable nutritional composition (C5/L52-60) comprising a protein, a source of digestible carbohydrates and a source of dietary fiber (Abstract) having an energy density of 0.7 -1.5 kcal/100ml (C5/L49-51) and dietary fiber in an amount of 1.2 g/100ml (C7/Example 1/L23). Brassart et al. also disclose that the source of fiber comprises 5-30% inulin (soluble fiber), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble fiber) (C4/L40-44).

Brassart et al. does not explicitly disclose that the nutritional composition comprises in excess of 2.5 g/100 ml or a soluble fiber including acacia gum.

Spivey-Krobath et al. teach that it was known to use a soluble fiber, including acacia gum, as part of a nutritional composition (p.5/L5). Given that acacia gum is a well known source of soluble fiber used for nutritional compositions, since Brassart et al. disclose a soluble fiber as part of a fiber blend, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of Brassart et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

While Brassart et al. disclose a nutritional composition with 1.2g/100ml dietary fiber the reference fails to disclose levels in excess of 2.5g/100ml. As viscosity is a variable that can be modified, among others, by adjusting the dietary fiber in the nutritional composition, the precise amount of dietary fiber would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing

unexpected results, the claimed content of dietary fiber cannot be considered critical.

Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of dietary fiber in the nutritional composition of Brassart et al. to obtain the desired balance between product viscosity and the nutritional benefits of dietary fiber (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding the intended use of the method, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Regarding claim 13, Brassart et al. disclose a method for preparing a nutritional composition comprising the steps of mixing a liquid or powdered reconstitutable nutritional composition comprising a liquid or powdered and reconstitutable nutritional composition (C5/L52-60) comprising a protein, a source of digestible carbohydrates and a source of dietary

fiber (Abstract) having an energy density of 0.7 -1.5 kcal/ml (C5/L49-51) and dietary fiber in an amount of 1.2 g/100ml (C7/Example 1/L23); and hydrating the components to provide a liquid mixture (C6/Example 1/L60-C7/L14). Brassart et al. also disclose that the source of fiber comprises 5-30% inulin (soluble fiber), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble fiber) (C4/L40-44).

Brassart et al. does not explicitly disclose that the nutritional composition comprises in excess of 2.5 g/100 ml or a soluble fiber including acacia gum.

Spivey-Krobath et al. teach that is was known to use a soluble fiber, including acacia gum, as part of a nutritional composition (p.5/L5). Given that acacia gum is a well known source of soluble fiber used for nutritional compositions, since Brassart et al. disclose a soluble fiber as part of a fiber blend, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of Brassart et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

While Brassart et al. disclose a nutritional composition with 1.2g/100ml dietary fiber the reference fails to disclose levels in excess of 2.5g/100ml. As viscosity is a variable that can be modified, among others, by adjusting the dietary fiber in the nutritional composition, the precise amount of dietary fiber would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed content of dietary fiber cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of dietary fiber in the nutritional composition

of Brassart et al. to obtain the desired balance between product viscosity and the nutritional benefits of dietary fiber (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Response to Arguments

6. Applicant's arguments filed 01/14/2009 have been fully considered but they are not persuasive.

Applicants argue that Spivey-Krobath et al. fails to disclose or suggest each and every element of claims 1-3, 6 and 8-15. However, Applicants' arguments with respect to claims 1-3, 6 and 8-15 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that Brassart et al. fails to disclose or suggest every element of claims 1-4 and 6-15. However, Applicants' arguments with respect to claims 1-4, and 8-15 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that neither Spivey-Krobath or Brassart disclose or suggest a nutritional composition comprising a source of dietary fiber, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble fiber and 20-40% by weight of oligosaccharides. Specifically, applicants assert that Spivey-Krobath et al. is primarily directed toward a nutritional composition for the prevention or treatment of an immune condition while Brassart et al. is entirely directed toward an enteral composition.

It is the Examiner's position that both Spivey-Krobath et al. and Brassart et al. disclose a nutritional composition comprising a source of dietary fiber. However, Spivey-Krobath et al. fails to explicitly disclose a source of fiber comprising the recited ratios including pea outer fiber (i.e. insoluble fiber). Brassart et al. teach an enteral composition which contains a protein source, a lipid source, a carbohydrate source and a fiber blend (Abstract). Brassart et al. teach that the fiber blend comprises 5-30% inulin (soluble non-starch polysaccharide), 10-40% fructo-oligosaccharides (i.e. oligosaccharide) and 20-50% pea outer fiber (i.e. non-soluble polysaccharide) (C4/L40-44). Brassart et al. teach that enteral compositions containing a balance of soluble and insoluble dietary fiber are less viscous and can be used for tube feeding (C1/L66-C2/L3). Further, enteral compositions containing the right balance of soluble to insoluble fibers are more stable (C1/L66-C2/L3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included a fiber blend including both soluble and insoluble fiber, as taught by Brassart et al, in the nutritional composition of Spivey-Krobath et al. for the purpose of producing a composition that is not too viscous for tube feeding and has increased stability.

With regards to acacia gum, given that Spivey-Krobath disclose the use of soluble fiber including both inulin and acacia gum (p.5/L5-6, p.10/Table 1), it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of modified Spivey-Krobath et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results.

Regarding the intended use of the method, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02. In this case, as set forth above, modified Spivey-Krobath et al. and modified Brassart et al. disclose a composition identical to that presently claimed.

Applicants explain that that the use of acacia gum as a soluble fiber, in addition to an insoluble fiber and oligosaccharides in a nutritional composition demonstrated good shelf-stability for 8 months and was judged to have a good taste. Applicants assert that there are unexpected benefits of improved intestinal transit, gut flora and gut comfort provided by use of the presently claimed composition.

Because there is substantial evidence to support determination of a prima facie case of obviousness over each of the applied prior art references, the burden of proof was properly shifted to the applicants to rebut the prima facie case by presenting persuasive arguments or evidence (e.g. unexpected results). *In re Mayne*, 104 F.3d 1339, 1343, 41 USPQ2d 1451, 1455 (Fed. Cir. 1997). ("With a factual foundation for its prima facie case of obviousness shown, the

burden shifts to applicants to demonstrate that their claimed fusion proteins possess an unexpected property over the prior art.")

Unexpected results must be established by factual evidence; mere argument or conclusory statements in the specification do not suffice. *In re Geisler*, 116 F.3d 1465, 1470, 43 USPQ2d 1362, 1365 (Fed. Cir. 1977) (quoting *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984)). Unexpected results must be established by comparing the claimed invention against the closest prior art. *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("[A]n applicant relying on comparative tests to rebut a prima facie case of obviousness must compare his claimed invention to the closest prior art."); accord *In re Merchant*, 575 F.2d 865, 869, 197 USPQ 785, 788 (CCPA 1978).

In this case, Applicants have not provided any evidence to show that the nutritional composition of modified Spivey-Krobath et al. or of modified Brassart et al. would not exhibit the same benefits as the presently claimed invention.

Further, "obviousness under 103 is not negated because the motivation to arrive at the claimed invention as disclosed by the prior art does not agree with appellant's motivation", *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990), *In re Tomlinson*, 150 USPQ 623 (CCPA 1966).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday; 7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794